

Attorney Docket No.: **BERN-0040**
Inventors: **Bernstein et al.**
Serial No.: **09/913,697**
Filing Date: **January 28, 2002**
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A' Sub P' cont.
cont. 6. (amended) The method of claim 5 wherein the composition comprises alpha 1-antitrypsin.

Sub P' A2 8. (amended) A pharmaceutical composition for prevention of photoaging and other sun-damage comprising alpha 1-antitrypsin or a serpin with alpha 1-antitrypsin like activity a second sunscreen or free radical scavenger, and a pharmaceutical additive.

REMARKS

Claims 1-10 are pending in the instant application. Claims 1-10 have been rejected as being anticipated under 35 U.S.C. 102(e) over the teachings of Lezdey et al. (U.S. Patent 6,096,327). Claims 1-6 and 8 have been amended. Claim 9 has been canceled in light of amendments to claim 8. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

The Rule 131 Declaration submitted by Applicants on March 12, 2003 was considered by the Examiner, but found not to place the application in condition for allowance. The Examiner maintains that the prior art reads on the claimed invention and the Declaration does not overcome the rejection.

Applicants respectfully traverse this rejection.

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The Examiner suggests that the Declaration states that a formulation of lubriderm: milk and alpha 1-antitrypsin was applied to transgenic mice but that the claimed invention, with the exception of claims 7 and 10 does not disclose the use of milk. Instead, the Examiner suggests that the claims are drawn to a composition containing a serine protease inhibitor.

The experiments described in paragraph 6 and 7 of Dr. Bernstein's Declaration, as well as the figure of Exhibit C, clearly demonstrate that the combination of milk and the serine protease inhibitor alpha 1-antitrypsin provided better protection of the skin than milk alone. As shown in the figure of Exhibit C, milk alone decreased elastin promoter activity (indicative of a protective effect against solar simulating radiation as taught in paragraph 4 of Dr. Bernstein's Declaration) by 1.5 fold. In comparison, when the serine protease inhibitor alpha 1-antitrypsin was added to milk, the protective effect increased to 11.5 fold. Clearly this huge increase in effect is demonstrative of a composition containing the serine protease inhibitor alpha 1-antitrypsin providing more protection against photodamage than vehicle alone. These experiments are also indicative of other serpins with alpha 1-antitrypsin like activities having a similar effect. Thus, the Declaration demonstrates conception and

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reduction to practice of a method of using a composition comprising alpha 1-antitrypsin or a serpin with alpha 1-antitrypsin like activities to protect the skin against photoaging, sun burn and skin cancer prior to the filing date of Lezdey et al.

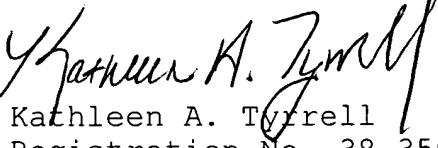
In an earnest effort to advance the prosecution of this case, Applicants have amended claims 1-6 and 8 to state that the composition comprises alpha 1-antitrypsin or a serpin with alpha 1-antitrypsin like activities. Claim 9 has been canceled in light of the amendments to claim 8. Support for this amendment is found in the specification at page 5, lines 4-16. This invention, as claimed, was clearly conceived and reduced to practice prior to the filing date of Lezdey et al. Accordingly, Lezdey et al. is not a valid prior art reference with respect to the instant claimed invention of claim 1 through 6 and 8 and withdrawal of this rejection is respectfully requested.

With respect to claims 7 and 10, the Examiner has acknowledged in the Advisory Action that Lezdey et al. does not disclose the use of milk. Accordingly, since milk is an element of these claims, this reference cannot anticipate these claims. See MPEP 2131. Accordingly, withdrawal of the rejection of

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claims 7 and 10 over the teachings of Lezdey et al. is also respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 9 has been canceled.

Claims 1-6 and 8 have been amended as follows:

1. (amended) A method of protecting humans exposed to sunlight against photoaging, sunburn and skin cancer comprising topically applying to skin of a human a ~~serine protease inhibitor composition comprising alpha 1-antitrypsin or a serpin with alpha 1-antitrypsin like activity~~ in an amount effective to protect the skin against photoaging, sun burn and skin cancer.

2. (amended) The method of claim 1 wherein the ~~serine protease inhibitor is composition comprises~~ alpha 1-antitrypsin.

3. (amended) The method of claim 1 wherein the ~~serine protease inhibitor composition~~ is applied prior to exposure of the skin to sunlight.

4. (amended) The method of claim 1 wherein the ~~serine protease inhibitor composition~~ is applied subsequent to exposure of the skin to sunlight.

5. (amended) A method of protecting individuals with a heightened sensitivity to the sun from damage resulting from the sun comprising topically applying to the skin of an individual with a heightened sensitivity to the sun a ~~serine protease~~

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inhibitor composition comprising alpha 1-antitrypsin or a serpin with alpha 1-antitrypsin like activity prior to exposure of the individual to the sun.

6. (amended) The method of claim 5 wherein the serine protease inhibitor is composition comprises alpha 1-antitrypsin.

8. (amended) A pharmaceutical composition for prevention of photoaging and other sun-damage comprising a serine protease inhibitor alpha 1-antitrypsin or a serpin with alpha 1-antitrypsin like activity, a second sunscreen or free radical scavenger, and a pharmaceutical additive.